



PATENT
Customer No. 22,852
Attorney Docket No. 6832.0018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Craig A. ROSEN et al.) Group Art Unit: 1631
Application No.: 09/833,245) Examiner: Michael L. Borin
Filed: April 12, 2001)
For: ALBUMIN FUSION PROTEINS)
)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated August 27, 2003, the Office required restriction under 35 U.S.C. § 121 between:

- Group I Claims 1-4, 13-20, drawn to conjugates of a protein or fragments thereof connected to albumin or fragments thereof, classified in class 530, subclass 350;
- Group II Claims 5-12, 13-20, drawn to conjugates wherein a protein or fragments thereof is inserted into albumin or fragment thereof, classified in class 530, subclass 350;
- Group III Claims 19-37, drawn to a kit comprising a polypeptide, classified in class 435, subclass 810;
- Group IV Claims 22-25, drawn to a method of treatment, classified in class 514, subclass 02;
- Group V Claim 26, drawn to a method of extending shelf life of a protein; and

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Group VI Claim 27-29, drawn to isolated nucleic acid, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.

The Office further required election of the following disclosed species for any one of the Groups elected above:

- A: For albumin, select full-length albumin, or albumin fragment or homolog; and
- B: If a fragment is elected, further select particular species from those listed in claim 6.

Applicants provisionally elect to prosecute Group I, claims 1-4, 13-20, drawn to conjugates of a protein or fragments thereof connected to albumin or fragments thereof, with traverse. Applicants further provisionally elect the full-length albumin species, also with traverse.

According to MPEP § 803, there are two requirements that must be met before a proper restriction requirement may be made: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Office if restriction is not required. Applicants respectfully submit that the Office has failed to establish the second requirement set forth in MPEP § 803. As discussed in more detail below, the subject matter of Groups I-III and all of the species in the instant application are being examined as a single group in five other related applications. Thus, there is strong evidence that it would not be a serious burden on the Office to search or to examine Groups I-III and the species together.

First, Applicants respectfully traverse the manner in which Groups I and II have been grouped. The Office appears to have distinguished Groups I and II in that Group I is directed to "[f]usion proteins comprising protein connected to N- or C-terminal of

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albumin" and that Group II is directed to "proteins comprising protein inserted into albumin." See Restriction Requirement, page 3. However, a reading of claim 1 (and its dependent claims 2-4), grouped within Group I, teaches that proteins comprising a therapeutic protein inserted into albumin are also encompassed within claims 1-4. Claim 1 reads, in part, as follows:

1. An albumin fusion protein comprising a member selected from the group consisting of:
 - (a) a therapeutic protein X and albumin comprising the amino acid sequence of SEQ ID NO:18;
 - (b) a therapeutic protein X and a fragment or variant of the amino acid sequence of SEQ ID NO:18; wherein said fragment or variant has albumin activity

There is no limitation within claim 1, groups (a) and (b), that a therapeutic protein be fused to the N- or C-terminus of albumin (or a fragment or variant thereof). Groups (a) and (b) could clearly encompass not only a therapeutic protein fused to the N- or C-terminus of albumin (or a fragment or variant thereof), but also a therapeutic protein inserted into albumin. Thus, Groups I and II should be examined together.

Moreover, in related applications, Application Nos. 09/833,111; 09/833,117; 09/833,118; 09/832,501; 09/832,929; 09/833,041, all filed on April 12, 2001, and all assigned to Examiner Hope A. Robinson, the subject matter of Groups I and II in this instant application are being examined together as a single group. Thus, Groups I and II should also be examined together in the instant application.

With respect to Group III (claims 19-37), which is directed to a kit, Applicants wish to point out that only claim 21 in the instant application is directed to a kit and that the instant application has only 29 claims. Applicants believe that Group III was intended to include only claim 21. Confirmation is kindly requested.

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Assuming that Group III includes only claim 21, Applicants assert that Group III should also be examined with Groups I and II. In the related applications disclosed above, the same subject matters as claims 1-21 in the instant application are being examined together. Thus, claims 1-21 should also be examined together in the instant application.

The election of species is also traversed on the same grounds as above. In the related applications, although the claims in all of the related applications recite full-length albumin (SEQ ID NO:18), or a fragment or a variant thereof, and the particular fragment species listed in claim 6, no election of species was required. Therefore, Applicants believe that no election of species should be required in the instant application.

It is therefore respectfully requested that the restriction requirement be reconsidered. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications on the non-elected inventions and/or to request rejoinder of appropriate claims once the subject matter of claims 1-4, 13-20 is found allowable.

Applicants have filed a Change of Correspondence Address enclosed herewith. Please forward all future correspondence in the instant application to the following address:

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U.S. Application No. 09/833,245
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Please grant any extensions of time required to enter this response and charge
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 25, 2003

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